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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,154	09/29/2003	John Landers	M0656.70098US00	7775

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EXAMINER

ZHOU, SHUBO

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/676,154

Applicant(s)

LANDERS ET AL.

Examiner

Shubo (Joe) Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-11, 17-31, 35, 36, 38-41, 47-56 and 140-166 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-5, 8-11, 17-31, 35-36, 38-41, 47-56, and 140-166 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Restriction/Election Requirement

1. This application contains claims directed to the following patentably distinct species in terms of the type of RCG involved in the claimed methods:

A1: a native RCG, as in claim 1, and

A2: a randomly primed PCR-derived RCG, as in claim 149.

Species A1 and A2 are distinct because each is prepared with a distinct method involving distinct steps. A native RCG is a genome that has a reduced complexity by moving some of the nucleic acids such as repetitive sequences, making the genome less complex but what is left is native, i.e. not altered. Species A2, however, involves PCR amplification with random priming, making the genome less complex but what is left is altered, i.e. PCR amplified.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, A1 or A2, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Species A2 contains claims directed to the following patentably distinct sub-species in terms of the type of PCR used to generate the RCG:

A2-1: using DOP-PCR to generate RCG, as in claim 159, and

A2-2: using adapter-PCR to generate RCG, as in claim 160

Sub-species A2-1 and A2-2 are distinct because each involves using distinct primers and produces distinct results. For A2-1, DOP primers are used and for A2-2, adapter primers are

used. In the end, while each produces a reduced genome, the structure of the reduced genomes are different.

If A2 is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed sub-species, A2-1 or A2-2, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

2. This application contains claims directed to the following patentably distinct species in terms of the type of samples involved in the claimed methods:

B1: genomic samples from a tumor, as in claim 9, and

B2: genomic samples selected randomly from a population, as in claim 11.

Species B1 and B2 are distinct because while each is a genomic DNA, the process of obtaining the genomic DNA samples from tumors and from an individual of a random population would be different, and the complexity of the genomic DNAs are also different –with the genomic DNA from tumors usually having multiple deletions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, B1 or B2, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

3. This application contains claims directed to the following patentably distinct species in terms of the type of the physical state of the nucleic acids for hybridization involved in the claimed methods:

C1: RCG is immobilized on a surface, as in claim 3, and

C2: the SNP-ASO is immobilized on a surface, as in claim 4.

Species C1 and C2 are distinct because the hybridization preparation would be different. In the case of C1, the RCG would be immobilized on a surface, and the SNP-ASO would be labeled as probes, whereas in the case of C2, it is just the opposite.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, C1 or C2, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

4. Applicant is advised that a reply to this requirement must include an identification of the species that are elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these species are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.
Patent Examiner



3/7/06